PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). | | | | |
|---|--|--|--|--|--|--|
| International Application No. | International Filing Da (day/month/year) | ite | Priority Date (day/month/year) | | | |
| PCT/AU2003/000839 | 30 June 2003 | | 28 June 2002 | | | |
| International Patent Classification (IPC) or | national classification a | nd IPC | | | | |
| Int. CL 7 A61N 1/05 | | | | | | |
| Applicant COCHLEAR LIMITED et al | | | | | | |
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| | | * * * . * | 2 D. T. Jan. Promining Authority and | | | |
| This international preliminary examina is transmitted to the applicant according | ition report has been pre ig to Article 36. | pared by this interns | tional Preliminary Examining Authority and | | | |
| 2. This REPORT consists of a total of | sheets, including this | cover sheet. | | | | |
| This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). | | | | | | |
| These annexes consist of a total of sheet(s). | | | | | | |
| 3. This report contains indications relation | g to the following items | | | | | |
| I X Basis of the report | I X Basis of the report | | | | | |
| II Priority | II Priority | | | | | |
| III X Non-establishment of o | III X Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | |
| IV Lack of unity of invent | IV Lack of unity of invention | | | | | |
| Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | |
| VI X Certain documents cite | æd | | | | | |
| VII Certain defects in the it | ne international application | | | | | |
| VIII X Certain observations on the international application | | | | | | |
| Date of submission of the demand Date of completion of the report | | | | | | |
| 14 August 2003 | | 26 October 2004 | | | | |
| Name and mailing address of the IPEA/AU | | Authorized Officer | | | | |
| AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2506, AUSTRALIA | | | | | | |
| E-mail address: pot@ipsustralia.gov.su Facsimile No. (02) 6265-3929 | | JOSEPH ÁRROUK | | | | |
| , , , , , , , , , , , , , , , , , , , | | Telephone No. (02) 6283 2219 | | | | |

International application No.

PCT/AU2003/000839

| 1. | Basis of the rep | ort | | | | | |
|--|--|---|--|--|--|--|--|
| 1. | 1. With regard to the elements of the international application:* | | | | | | |
| | the international application as originally filed. | | | | | | |
| | X the description | pages 1-32, as originally filed. | | | | | |
| | ક્ | pages , filed with the demand. | | | | | |
| | X | pages, received on with the letter of | | | | | |
| | X fine claims, | pages , as originally filed. | | | | | |
| | | pages 33 - 38, as amended (together with any statement) under Article 19, | | | | | |
| | | pages , filed with the demand, | | | | | |
| , | | pages , received on with the letter of | | | | | |
| | X the drawings, | pages 1/3-3/3, as originally filed, | | | | | |
| | | pages , filed with the demand, | | | | | |
| | V. | pages , received on with the letter of | | | | | |
| | the sequence lis | ting part of the description: | | | | | |
| | 4. | pages , as originally filed | | | | | |
| | | pages , filed with the demand | | | | | |
| | | pages , received on with the letter of | | | | | |
| 2. | With regard to the land | guage, all the elements marked above were available or furnished to this Authority in the language in | | | | | |
| | The second section of the section of | * ************************************ | | | | | |
| | corse crements were a | variable or furnished to this Authority in the following language which is: | | | | | |
| | us language of : | a translation furnished for the purposes of international search (under Rule 23.1(b)). | | | | | |
| | inclanguage of | publication of the international application (under Rule 48.3(b)). | | | | | |
| | the language of t and/or 55.3). | he translation furnished for the purposes of international preliminary examination (under Rules 55.2 | | | | | |
| 3. | With regard to any nue preliminary examina | lectide and/or amino acid sequence disclosed in the international application, the international tion was carried out on the basis of the sequence listing: | | | | | |
| | contained in the | nternational application in written form. | | | | | |
| | discussion of the second of th | h the international application in computer readable form. | | | | | |
| | | | | | | | |
| | - Delication - Control - C | nently to this Authority in written form. | | | | | |
| | furnished subsequ | sently to this Authority in computer readable form. | | | | | |
| | The statement the international appl | if the subsequently furnished written sequence listing does not go beyond the disclosure in the ication as filed has been furnished. | | | | | |
| | The statement the been furnished | t the information recorded in computer readable form is identical to the written sequence listing has | | | | | |
| | The amendments | have resulted in the cancellation of: | | | | | |
| | the descr | | | | | | |
| | the claim | s, Nos. | | | | | |
| | the drawi | ngs, sheets/fig. | | | | | |
| , , | This report has be | on established as if (some of) the amendments had not been made, since they have been considered to | | | | | |
| **** | | Acoustic as tricu, as national in the Supplemental Box (Rule 71).2(c)).** | | | | | |
| Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17). | | | | | | | |
| • | Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report | | | | | | |

International application No.

PCT/AU2003/000839

| 8 | The questions whether the claimed invention appears to be novel, to involve an inventive siep (to be nonobvious), or to lindustrially applicable have not been examined in respect of: |
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| | |
| , | the entire international application, |
| diament. | claums Nos: 26 |
| | because: |
| e annual | the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify): |
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| | |
| 3 | the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that n |
| | meaningful opinion could be formed (<i>specify</i>): |
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| | |
| X | the claims, or said claims Nos. 26 are so inadequately supported by the description that no meaningful opinion cou |
| | no international search report has been established for said claim Nos. |
| 1316 | eamingful international preliminary examination cannot be carried out due to the failure of the nucleofide and/or amino sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions: |
| id: | paymon and manner Col the Administrative Institutions. |
| id: | the written form has not been furnished or does not comply with the standard. |

International application No.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

| 1. Statement | | |
|-------------------------------|------------------------|-----|
| Novelty (N) | Claims 1 - 25, 27 - 37 | YES |
| | Claims | МО |
| Inventive step (IS) | Claims 1-25, 27-37 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-25, 27-37 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

Reference is made to the following document cited in the corresponding ISR:

(a) WO 2003/035168 A1 (COCHLEAR LIMITED), 1 May 2003

NOVELTY (N):

Claims 1 - 25, 27 - 37

The invention defined in claims 1 - 25, 27 - 37 of the present application primarily defines an implantable tissue stimulating device comprising an elongated carrier member having at least a first lumen and further including one or more optic fibres positioned along a length of the first lumen.

Citation (a) discloses an electrode array having a plurality of electrodes mounted thereon in a longitudinal array. The elongated member has a stiffening element extending at least partially therethrough. The stiffening element can extend through a lumen formed in the elongated member and the lead. The lumen preferably extends axially through the elongated member and the lead.

The features defined in claims 1 - 16, 20 - 25, 27 - 37 are not found in citation (a). See however the indication contained in box VI "Certain documents cited" with regard to claims 17 and 18.

INVENTIVE STEP (IS):

As above.

International application No.

| | | | PU1/AU2003/000839 |
|---|--|-----------------------------------|--|
| VI. Certain documents cited | | | 3 |
| 1. Certain published documents (| Rule 70.10) | | |
| Application No. Patent No. | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (valid claim) (day/month/year) |
| P, X WO 2003/035168 A1 | 1 May 2003 | 25 October 2002 | 26 October 2001 |
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| The above-listed prior art doc | ument discloses all the fea | stures defined in claims 17 and | 18 of the present application |
| | | | |
| Sou. Acera | or, rage 1, and 18 - page t | 5, line 30; Page 7, line 22 - pag | 2 10, line 8. |
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| 2 Non-market Section 18 18 18 | ************************************** | | |
| Non-written disclosures (Rule Kind of non-written disclosur | | written disclosure Date | of written disclosure referring to |
| | | nonth/year) | non-written disclosure |
| | | | (day/month/year) |
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International application No.

PCT/AU2003/000839

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

 Claim 12 is not clear because I cannot find an antecedent to the following features: "The implantable tissue stimulating device", page 34, line 17; and "the one or more optic fibres", page 34, line 17.

Furthermore, the invention defined in claim 12 is not fairly based on what is described in the specification. Claim 12 does not define the invention described because it omits all the essential features. Claim 12 only defines non-essential features which, are described in the preferred embodiments.

It appears that claim 12 was intended to a dependent on previous claim.

- 2. The invention defined in claim 17 is not fairly based on what is described in the specification. Claim 17 does not define the invention described because it omits the feature of the elongated carrier including "one or more optic fibres positioned along a length of said at least a first lumen", which from page 5, lines 5 6, page 6, line 18, and page 6, line 36, appears to be essential to the invention.
- 3. The invention defined in claim 26 is not fairly based on what is defined in the specification. Claim 26 does not define the invention described because it omits almost all the essential features of the invention.

Due to the extreme degree of lack of fair basis I cannot understand the scope of the monopoly being claimed because the definition of the invention is so broad in scope. Therefore, I cannot form an opinion with regard to novelty and inventive step (see Box III).